DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 15, 2015

Stryker Corporation
% Garry T. Hayeck, Ph.D.
Senior Regulatory Affairs Specialist
Stryker Spine
2 Pearl Court
Allendale, New Jersey 07401

Re: K142741
Trade/Device Name: OASYS® System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 19, 2014
Received: December 22, 2014

Dear Dr. Hayeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142741

Device Name
OASYS® System

Indications for Use *(Describe)*

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput-T3), the STRYKER Spine Oasys System is intended for:

• Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
• Spondylolisthesis
• Spinal Stenosis
• Fracture/Dislocation
• Atlanto/axial fracture with instability
• Occipitocervical dislocation
• Revision of previous cervical spine surgery
• Tumors

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1 -T3). They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The Stryker Spine OASYS® System can be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors and transition rods.

The Stryker Spine OASYS® System can also be linked to the polyaxial screws of Xia® II and Xia® 3 System via the saddle connector.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: OASYS® System	
Submitter	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person	Garry T. Hayeck, Ph.D. Senior Regulatory Affairs Specialist Phone: 201-760-8043 Fax: 201-962-4043 E-mail: garry.hayeck@stryker.com
Date Prepared	December 16, 2014
Trade Name	OASYS® System
Common Name	Spinal Fixation Appliances
Proposed Class	Class II
Classification Name, Codification	Spinal Interlaminal Fixation Orthosis, 21 CFR § 888.3050
Product Codes	KWP
Predicate Devices	Primary Predicate Device: Stryker Spine OASYS® System: K111719
Device Description	The Stryker Spine OASYS® System is comprised of rods, polyaxial screws, bone screws, hooks, connectors, and occiput plates. The components are available in a variety of lengths in order to accommodate patient anatomy. The components are fabricated from Titanium alloy and CP Titanium and are provided non-sterile. The subject system also offers Vitallium® rods. The Stryker Spine OASYS® System can be linked to the Stryker Spine Xia® family and Xia 4.5 Systems and SR90D System.
Indications for Use	When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput-T3), the STRYKER Spine Oasys System is intended for: • Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) • Spondylolisthesis • Spinal Stenosis • Fracture/Dislocation • Atlanto/axial fracture with instability • Occipitocervical dislocation • Revision of previous cervical spine surgery • Tumors When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine. The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1 -T3). They are not intended to be placed in the cervical spine.

	The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine. The Stryker Spine OASYS® System can be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors and transition rods. The Stryker Spine OASYS® System can also be linked to the polyaxial screws of Xia® II and Xia® 3 System via the saddle connector.
Summary of Technological Characteristics	The subject OASYS® System shares the same materials, geometries, and fundamental scientific technologies as predicate OASYS® Systems. The proposed new screws are identical to previously cleared OASYS® screws with the exception that they incorporate a square drive mechanism.
Summary of Performance Data	An engineering analysis was performed to demonstrate that the addition of screws with a modified drive mechanism does not affect the performance of the OASYS® System.
Conclusion	The devices, methodologies, and materials used in this system are equivalent to previously cleared OASYS® Systems. As such, this system is substantially equivalent to the legally marketed predicate devices.